



FCC/FDA MEETING ON WIRELESS MEDICAL TECHNOLOGIES

PROMOTING EMC

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I. Understanding the Role of Federal Agencies in EMC Regulation

➤ FCC –

- Protection of licensed radio services
- Radiation safety protection of the public

➤ FDA –

- Ensuring safety and efficacy of medical devices (including EMI susceptibility)

II. Wireless Medical Technologies – EMC Issues

- Spectrum allocation – where can WMT be deployed?
- Limitations – power, range, reliability
- Protection – licensed vs unlicensed use
- International harmonization
- Cognitive radio (future)

III. FCC Challenges

- Ensuring spectrum compatibility – in band and out of band
- Tools – emissions standards, testing procedures
- Limited authority – receiver and susceptibility standards
- Restricted bands – NTIA coordination

IV. FDA Challenges - 2007 Guidance on Wireless Devices

- Risk management and EMC
 - International Standards (IEC 60601-1-2)
 - Coexistence, quality, data integrity and security
- Design, development & validation re EMC
- Labeling
 - EMC standards, testing, RF effects, separation distance
- Purchasing
- Corrective Actions
- Servicing

V. Manufacturer Challenges

- WMT applications – monitoring, tracking and controlling
- Spectrum “sweet spots” and trade offs
- Medical reimbursement
- Liability issues